IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 09-403-01, 02**
NORIAN CORPORATION **SYNTHES, INC.**	:	

GOVERNMENT'S GUILTY PLEA AND SENTENCING MEMORANDUM

I. INTRODUCTION

On October 4, 2010, the United States Attorney for the Eastern District of Pennsylvania filed a 112-count superseding information ("the information") against the defendants, Synthes, Inc., a major medical device manufacturer doing business in West Chester PA, and its subsidiary, Norian Corporation.[1] The information charges defendant Synthes with one misdemeanor count of introducing into interstate commerce adulterated and misbranded medical devices, in violation of Title 21, United States Code, Sections 331(a), 352(f)(1), 352(o), 351(f)(1)(B) and 333(a)(1). The information charges defendant Norian Corporation ("Norian"), a

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[1] As to defendants Synthes and Norian, the information supersedes the original indictment in the case, returned on June 10, 2009. The original 97-count indictment had charged Synthes, the parent corporation, with 44 misdemeanor counts of introducing into interstate commerce adulterated and misbranded medical devices, in violation of Title 21, United States Code, Sections 331(a), 352(f)(1), 352(o), 351(f)(1)(B) and 333(a)(1). The original indictment had further charged Norian, the subsidiary, with with 52 felony violations. Count one of the indictment contained essentially the same conspiracy charge as contained in the information: it alleged that defendant Norian and others participated in a dual-object conspiracy: to impair and impede the lawful functions of the Food and Drug Administration ("FDA"); and to commit offenses against the United States, all in violation of Title 18, United States Code, Section 371. The indictment had charged Norian with 44 felony counts of introducing adulterated and misbranded medical devices into interstate commerce with the intent to defraud, in violation of Title 21, United States Code, Sections 331(a), 352(f)(1), 352(o), 351(f)(1)(B) and 333(a)(2), and seven counts of making false statements to an FDA investigator during an official inspection, in violation of Title 18, United States Code, Section 1001.

wholly owned subsidiary of Synthes, with one felony and 110 misdemeanor violations. Count one alleges that defendant Norian and others participated in a dual-object conspiracy: to impair and impede the lawful functions of the Food and Drug Administration ("FDA"); and to commit offenses against the United States, all in violation of Title 18, United States Code, Section 371. Defendant Norian is further charged with 110 misdemeanor counts of introducing adulterated and misbranded medical devices into interstate commerce, in violation of Title 21, United States Code, Sections 331(a), 352(f)(1), 352(o), 351(f)(1)(B) and 333(a)(2). The charges arose out of the criminal conduct described in detail in the information, filed this date.

Defendants Synthes and Norian have notified the United States through their counsel, Donald J. Goldberg, Esquire and James T. Smith, Esquire, respectively, that each corporation intends to enter a plea of guilty to counts of the information in which it is charged. The guilty plea agreements, executed copies of which are attached as Exhibits A and B to this memorandum, were made pursuant to Fed.R.Crim.P. 11(c)(1)(C). Accordingly, in each case, the parties respectfully request that the Court impose the specific, agreed-upon sentence as the appropriate disposition of this case. For this reason, if acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Synthes and Norian be sentenced at the time their guilty pleas are entered.

II. PLEA AGREEMENTS

Executed copies of the plea agreements are attached as Exhibits A and B to this Memorandum.

III. MAXIMUM PENALTIES

For Synthes: a fine of $200,000, or twice the gross gain or gross loss, whichever is greater; $469,800 in criminal forfeiture; a special assessment of $125; and a five-year term of probation. The terms and conditions of any Court supervision may be changed and extended by the Court if the defendant were to violate any of its terms and conditions.

For Norian: a fine of $22,500,000, or twice the gross gain or gross loss, whichever is greater; $469,800 in criminal forfeiture; a special assessment of $14,150; and a five-year term of probation. The terms and conditions of any Court supervision may be changed and extended by the Court if the defendant were to violate any of its terms and conditions.

IV. THE AGREED-UPON SENTENCES UNDER RULE 11(c)(1)(C)

Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentences are as follows:

A. For Synthes, the parent corporation:

1. Synthes agrees to pay the special assessment in the amount of $125 on the date of sentencing.

2. Synthes agrees to pay $669,800 to resolve the Superseding Information, of which $200,000 will be applied as a criminal fine, and $469,800 will be applied as substitute assets to satisfy the forfeiture obligation described in paragraph 4(C) below. Synthes will pay these amounts within 3 business days after the date of sentencing. Synthes and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations. Synthes and the government agree that no order of restitution is appropriate in light of the anticipated, separate civil settlement agreement involving

the same conduct described in the Superseding Information, and to avoid unduly complicating and prolonging the sentencing process.

3. Synthes agrees that as a result of its acts or omissions, the forfeitable property, that is the medical devices that were illegally test marketed and promoted, are no longer available for forfeiture because the devices cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, Synthes agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of $469,800 as substitute assets for the pertinent devices. Synthes agrees that, within 3 business days after the date of sentencing, Synthes will make payment to the United States, by means of a wire transfer to the United States Marshals Service or check payable to same, in the amount of $469,800, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

4. In light of a Corporate Integrity Agreement between Synthes and the Office of Inspector General of the United States Department of Health and Human Services, Synthes will not be placed on probation.

B. <u>For Norian, the subsidiary of Synthes</u>:

1. Norian agrees to pay the special assessment in the amount of $14,150 on the date of sentencing.

2. Norian agrees to pay a criminal fine of $22,500,000 to resolve the Superseding Information. Norian will pay this amount within 10 business days of the date of sentencing. Norian waives any and all defenses and objections in this matter that might be

available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. Norian and the government agree that no order of restitution is appropriate in light of the anticipated, separate civil settlement agreement involving the same conduct described in the Superseding Information, and to avoid unduly complicating and prolonging the sentencing process.

3. In light of the anticipated exclusion of Norian from participation in Federal health care programs by the Office of Inspector General of the United States Department of Health and Human Services pursuant to 42 U.S.C. §§ 1320a-7 et seq., Norian will not be placed on probation.

V. ELEMENTS OF THE OFFENSES

A. Conspiracy in violation of 18 U.S.C. § 371 (Count One – Norian)

Section 371, the general federal conspiracy statute, provides as follows: :

> If two or more persons conspire either to commit any offense against the United States, or to defraud the United States, or any agency thereof in any matter or for any purpose, and one or more of such persons do any act to effect the object of the conspiracy, each shall be [subject to criminal penalties].

18 U.S.C. § 371.

Section 371 refers to two types of conspiracies: (1) conspiracy to commit a substantive offense proscribed by another statute (the " 'offense' clause"); and (2) conspiracy to defraud the United States (the " 'defraud' clause"). See United States v. Vazquez, 319 F.2d 381, 384 (3d Cir.1963). While the "offense" clause requires reference to another part of the criminal code, the "defraud" clause does not, because the substantive offense (fraud) is contained in the statute itself. United States v. Alston, 77 F.3d 713, 718 (3d Cir. 1996).

To establish a Klein conspiracy under the "defraud" clause of 18 U.S.C. § 371, the government must prove the following elements:

(1) the existence of an agreement,

(2) an overt act by one of the conspirators in furtherance of the [agreement's] objectives, and

(3) an intent on the part of the conspirators to agree, as well as to defraud the United States.

Alston, supra; United States v. Shoup, 608 F.2d 950, 956 (3d Cir.1979).[2]

To establish a conspiracy to commit an offense against the United States under the "offense" clause of 18 U.S.C. § 371, the government must prove the following elements:

(1) the existence of an agreement,

(2) an overt act by one of the conspirators in furtherance of the [agreement's] objectives, and

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[2] In order for a Klein conspiracy to exist, an agreed-upon objective must be to impede the federal agency in question. See Ingram v. United States, 360 U.S. 672, 679-80 (1959) (in a Klein conspiracy aimed at the IRS, an agreed-upon objective must be to impede the IRS). This need not be the sole or even a major objective of the conspiracy. Id. In the end, the evidence must be sufficient to prove beyond a reasonable doubt that impeding the federal agency was one of the conspiracy's objects and not merely a foreseeable consequence or collateral effect. See United States v. Goldberg, 105 F.3d 770, 774 (1st Cir.1997) ("mere collateral effects of jointly agreed-to activity, even if generally foreseeable, are not mechanically to be treated as an object of the conspiracy.") United States v. Adkinson, 158 F.3d 1147, 1154 (11th Cir.1998) (the government must "prove that there was an agreement whose purpose was to impede the IRS (the conspiracy), and that each defendant knowingly participated in that conspiracy." (emphasis omitted)).

(3) an intent on the part of the conspirators to agree, as well as to commit the offense in question (here, to make knowingly false material statements within the jurisdiction of a federal agency, the Food and Drug Administration).

B. Misdemeanor Shipment of Adulterated and Misbranded Medical Devices into Interstate Commerce, in violation of 21 U.S.C. §§ 331(a), and 333(a)(1) (Count Two – Synthes; Counts Three through 112 – Norian)

The Food, Drug and Cosmetic Act ("FDCA") prohibits introduction into interstate commerce of any medical device which is either adulterated or misbranded. (Title 21, United States Code, Section 331(a).) Under Section 351 of the FDCA, a medical device is adulterated under several circumstances, including when it has been introduced into interstate commerce without first obtaining premarket approval by the FDA, or when it is required to have an approved investigational device exemption ("IDE") and does not have an approved IDE in effect.[3] (Title 21, United States Code, Section 351(f)(1)(B).) Premarket approval can only be obtained by submitting a premarket approval ("PMA") application. Premarket approval is

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[3] There are two ways in which a medical device manufacturer may obtain the FDA's permission to market a device in the United States. The longer and usually more expensive route is premarket approval, often called "approval," obtained by means of a premarket approval ("PMA") application. The shorter and usually less expensive route is premarket notification, often called "clearance" or "510(k) approval." As part of the pre-market approval or clearance process, the FDA often requires device manufacturers to submit the results of clinical trials or investigations, that is, research involving one or more human subjects to determine the safety of effectiveness of the device.

Manufacturers of significant risk devices cannot legally conduct clinical trials or investigations in the United States without first obtaining the FDA's permission to do so, by way of an IDE. Before beginning a clinical trial of a significant risk device, the device manufacturer is required to obtain the FDA's approval of the IDE, and a multi-disciplinary group of professionals with backgrounds in areas like science, medicine and bioethics called an Institutional Review Board ("IRB") is required to approve the investigational plan and informed consent form, so that the clinical trial is properly monitored and the human subjects properly protected.

required if, among other things, the device is a class III device – the sort of device that is subject to the most stringent regulatory requirements – and it has not been previously approved through the premarket approval process. If the FDA has never reviewed and classified the device, or if a previously reviewed device (including a class II device) is changed or modified in a way that could significantly affect its safety or effectiveness, or has a change in intended use, the device is presumptively a class III device requiring a PMA until stated otherwise by the FDA.

Introduction of an adulterated device into interstate commerce is either a misdemeanor or a felony violation of the FDCA. Misdemeanor liability is strict; no proof of intent is required. (Title 21, United States Code, Section 333(a)(1).) A felony conviction requires either proof of an intent to defraud or mislead, or a prior conviction under § 333. (Title 21, United States Code, Section 333(a)(2).)

In order to prove the crime of misdemeanor adulteration, the government must establish the following elements beyond a reasonable doubt:

(1) that Norian XR was a medical device

(2) that Norian XR was adulterated, in that it

(a) had been introduced into interstate commerce without first obtaining premarket approval by the FDA, or

(b) was required to have an approved IDE and did not have an approved IDE in effect; and

(3) that Norian XR was introduced into interstate commerce.

Under section 352 of the FDCA, a device is "misbranded" under several circumstances, including when its label does not bear adequate directions for its intended use,

and when the device manufacturer has failed to provide the FDA with pre-market notification of a new or non-FDA-cleared intended use ninety days prior to introducing the device into interstate commerce for such use. (Title 21, United States Code, Section 352(f), (o).)

Like the crime of adulteration, introduction of a misbranded device into interstate commerce can be either a misdemeanor or a felony violation of the FDCA. Misdemeanor liability is strict; no proof of intent is required. (Title 21, United States Code, Section 333(a)(1).) A felony conviction requires either proof of an intent to defraud or mislead, or a prior conviction under § 333. (Title 21, United States Code, Section 333(a)(2).)

In order to prove the crime of misdemeanor misbranding, the government must establish the following elements beyond a reasonable doubt:

(1) that Norian XR was a medical device

(2) that Norian XR was misbranded, in that it

(a) lacked adequate directions for the use intended by Norian and Synthes (that is, the treatment of VCFs), or

(b) Norian and Synthes failed to provide the FDA with pre-market notification of a new or non-FDA-cleared intended use 90 days prior to introducing the device into interstate commerce for such use (that is, the treatment of VCFs), and

(3) that Norian XR was introduced into interstate commerce.

VI. SENTENCING GUIDELINES

The Sentencing Guidelines, which are now advisory, do not apply to this case because the applicable guideline provision, § 2N2.1, is not among those to which the guidelines for organizations apply. See U.S.S.G. § 8C2.1(a). The parties have agreed that Synthes and Norian will pay the maximum penalties allowed by statute.

VII. SUMMARY OF EVIDENCE

A. The Facts That The Government Would Prove At Trial

The facts that the government would prove at trial are set out in detail in the information filed this date.

B. The Ultimate Facts to Which The Defendants Stipulated in Their Plea Agreements

In paragraph 8a through i of the plea agreement of Synthes, and in paragraph 7a through i of the plea agreement of Norian, the defendants stipulated that, if the cases against them had gone to trial, the United States would have proven the following ultimate facts:

(a) Synthes and its subsidiary, Norian, marketed Norian CRS, Norian SRS and Norian XR, each of which was a medical device within the meaning of 21 U.S.C. § 321(h)(1), and a significant risk device within the meaning of 21 C.F.R. § 812(m)(1).

(b) Significant risk devices cannot be clinically tested without prior approval of the FDA, which approval is given through an investigational device exemption (IDE).

(c) In the context of medical devices, clinical testing means research on one or more human subjects to determine the safety or effectiveness of the device.

(d) Shipments of a medical device in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the medical device's intended uses. A manufacturer cannot market its device for a new intended use without notifying the FDA via a new 510(k) premarket notification. The failure to notify the FDA of a new intended use misbrands the device.

(e) In December 2001, Norian SRS, a calcium phosphate compound, was cleared via the 510(k) process by the FDA as a bone void filler, to fill only those bony voids that were not intrinsic to the stability of the bony structure, in the extremities, spine and pelvis. The Norian SRS label stated further that SRS was not to be mixed with any other substance. In December 2002, the successor device, Norian XR, which consisted of calcium phosphate with barium sulfate added for extra radiopacity, was cleared via the Special 510(k) process by the FDA, also as a bone void filler, with an indication statement identical to that of SRS. The Norian XR label further contained a warning: "not intended for treatment of vertebral compression fractures."

(f) Earlier, but no later than May 2002, Synthes and Norian learned that the FDA was concerned over the imprecision of the spine indication in the then-current indication for use of bone void fillers, and that the FDA understood that some surgeons, as part of their practice of medicine, were using bone void fillers in the spine for load-bearing indications. The FDA asked that Synthes and Norian – in their pre-market notification to the FDA seeking clearance of Norian XR -- provide additional labeling for Norian XR that specified that spinal load-bearing indications, such as vertebroplasty, were not included in the product's indication for use. Defendants Synthes and Norian then promised the FDA that the companies would not promote Norian XR for vertebroplasty or other spinal load-bearing indications without the appropriate regulatory authority. The FDA continued to request such labeling until Synthes submitted the warning against vertebral compression fracture ("VCF") use that became a part of the Norian XR label.

(g) Between August 2002 and December 2002, Synthes and Norian trained spine surgeons to mix Norian SRS with barium sulfate and to use the resulting medical device in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian SRS stated that the product was not to be mixed with any other substance. This training of surgeons to mix Norian SRS with barium sulfate for the treatment of VCFs violated 21 U.S.C. §§ 351(f)(1)(B), 352(o) and 352(f)(1) because the mixing made SRS a new device that required premarket approval or clearance for this new intended use, and that lacked adequate directions for such use.

(h) Between August 2003 and January 2004, Synthes and Norian trained spine surgeons to use Norian XR in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. This training took place as part of an illegal so-called "test market" for Norian XR. As part of the XR "test market," Synthes and Norian directed the Synthes Spine sales force to gather clinical data about

surgeries that the "test market" surgeons performed, so that Synthes and Norian could document the results of surgeries to treat VCFs, in order to assess the risk level of using Norian XR to treat VCFs, and determine whether that risk level was too high. This unauthorized clinical testing of Norian XR for the treatment of VCFs violated 21 U.S.C. § 351(f)(1) because such testing of a significant risk device required the prior approval of the FDA, through an IDE.

(i) Between December 2002 and January 2004, Synthes and Norian promoted Norian XR for use in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. The promotion of Norian XR for this additional intended use violated 21 U.S.C. § 351(f)(1), because Norian XR's labeling did not bear adequate directions for each of the device's intended uses, and in fact, warned against the intended use of treating VCFs.

In addition, in paragraph 7j of the plea agreement of Norian, defendant Norian stipulated that, if the case against Norian had gone to trial, the United States would have proven the following additional ultimate facts:

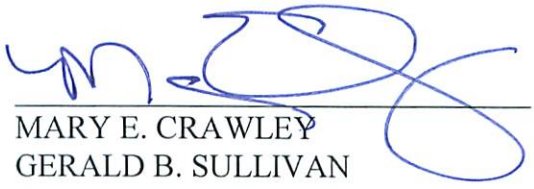
(j) In May and June 2004, Synthes and Norian were the subject of an unannounced inspection by the FDA. During the inspection, employees of Synthes and Norian knowingly made material false statements to the FDA investigator, concerning the training of spine surgeons to mix Norian SRS with barium sulfate for the treatment of VCFs, and the illegal so-called "test market" for Norian XR.

The United States respectfully submits that the summary of evidence provided above and in the information constitutes a factual basis for the guilty pleas by Synthes and Norian to Counts One through 112 of the information. The United States respectfully requests that the Court take into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, and

impose the sentences requested above.

Respectfully submitted,

ZANE DAVID MEMEGER
United States Attorney



MARY E. CRAWLEY
GERALD B. SULLIVAN
Assistant United States Attorneys

CERTIFICATE OF SERVICE

I hereby certify that I have caused to be served a true and correct copy of the annexed Guilty Plea and Sentencing Memorandum on counsel for the defendants Synthes and Norian by electronic filing:

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Assistant United States Attorney

DATE: 10/4/10

EXHIBIT A

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 09 - 403 - 01**
NORIAN CORPORATION	:	

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant, Norian Corporation (hereinafter "Norian"), and Norian's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the United States Department of Justice.

1. Norian agrees to plead guilty to Counts One and Three through 112 of a Superseding Information, waiving prosecution by indictment, charging it with:

A. one count of conspiring:

I. to defraud the United States and its agencies by impeding, impairing, and defeating the lawful functions of the Food and Drug Administration ("FDA") to protect the health and safety of the public by ensuring that medical devices marketed and distributed in the United States were safe and effective for their intended uses, that the labeling of such devices bore true and accurate information, and that clinical investigation of significant risk devices on humans was overseen by the FDA; and

ii. to commit an offense against the United States with the intent to defraud or mislead, by introducing into interstate commerce an adulterated and misbranded medical device, Norian XR, for the intended use of treating vertebral compression

fractures ("VCFs") through vertebroplasty and kyphoplasty procedures, when Norian XR had not received either pre-market approval or pre-market clearance for that intended use, and when the label of Norian XR bore a warning that the device was "not intended for treatment of vertebral compression fractures," in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2); and

iii. to commit an offense against the United States by knowingly and willfully making materially false, fictitious, and fraudulent statements and representations and falsifying and concealing material facts in a matter within the jurisdiction of the Food and Drug Administration ("FDA"), an agency of the executive branch of the United States, in violation of Title 18, United States Code, Section 1001, all in violation of Title 18, United States Code, Section 371; and

B. 110 counts of introducing into interstate commerce medical devices that were adulterated pursuant to Title 21, United States Code, Section 351(f)(1)(B), and misbranded pursuant to Title 21, United States Code, Sections 352(f), (o), which are misdemeanor violations of Title 21, United States Code, Sections 331(a) and 333(a)(1),

all arising from Norian's illegal test marketing and promotion of its medical devices Norian SRS and Norian XR in the United States between May 2002 and July 2004. Norian further acknowledges its waiver of rights, as set forth in Exhibit A to this agreement.

2. This agreement is conditioned upon the following: (a) the defendant's parent, Synthes, Inc. ("Synthes"), entering a guilty plea in this case; and (b) acceptance of that plea by the United States District Court at the time of the guilty plea hearing. If conditions 2(a) and 2(b) are not satisfied, or if Synthes subsequently seeks to withdraw its guilty plea, the United

States, in its sole discretion, will be released from all its obligations under this agreement. In addition, if defendant Synthes breaches its plea agreement, the United States, in its sole discretion, may void this defendant's plea agreement.

3. With regard to the Superseding Information to be filed pursuant to this agreement, defendant Norian waives all defenses based on speedy trial under the Constitution or Speedy Trial Act, and any statutes of limitations. The defendant agrees that prosecution of the offense described in paragraph one above is timely as of the date that this agreement is signed and as of the date that the guilty plea will be entered in District Court. In the event that this agreement is not consummated, any party withdraws from it, or it is otherwise not fully carried out, including the following circumstances described in subparagraphs (a) through (h) of this paragraph, the defendant waives all defenses based on speedy trial and any statute of limitations with respect to the charges set forth in the Superseding Information to be filed pursuant to this agreement, for 90 days from the latest of any of these events: (a) Norian's guilty plea is not accepted by the Court for any reason; (b) Synthes's guilty plea is not accepted by the Court for any reason; © Norian's conviction is later vacated for any reason; (d) Synthes's conviction is later vacated for any reason; (e) Norian violates this agreement; (f) Synthes violates its plea agreement; (g) Norian's plea is later withdrawn; or (h) Synthes's plea is later withdrawn.

4. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentence is as follows:

A. Norian agrees to pay the special assessment in the amount of $14,150 on the date of sentencing.

B. Norian agrees to pay a criminal fine of $22,500,000 to resolve the Superseding Information. Norian will pay this amount within 10 business days of the date of sentencing. Norian waives any and all defenses and objections in this matter that might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment. Norian and the government agree that no order of restitution is appropriate in light of the anticipated, separate civil settlement agreement involving the same conduct described in the Superseding Information, and to avoid unduly complicating and prolonging the sentencing process.

C. In light of the anticipated exclusion of Norian from participation in Federal health care programs by the Office of Inspector General of the United States Department of Health and Human Services pursuant to 42 U.S.C. §§ 1320a-7 et seq., Norian will not be placed on probation.

5. Norian waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

6. Norian understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of $22,500,000, or twice the gross gain or gross loss, whichever is greater; $469,800 in criminal forfeiture; a special assessment of $14,150; restitution, if ordered by the Court; and a five-year term of Court supervision. Norian further understands that the terms and conditions of any Court supervision

may be changed, and extended, by the Court if Norian violates any of the terms and conditions of that supervision.

7. With respect to Norian's conduct, the parties stipulate to the following facts and basis for the plea and criminal fine:

(a) Synthes and its subsidiary, Norian, marketed Norian CRS, Norian SRS and Norian XR, each of which was a medical device within the meaning of 21 U.S.C. § 321(h)(1), and a significant risk device within the meaning of 21 C.F.R. § 812(m)(1).

(b) Significant risk devices cannot be clinically tested without prior approval of the FDA, which approval is given through an investigational device exemption (IDE).

(c) In the context of medical devices, clinical testing means research on one or more human subjects to determine the safety or effectiveness of the device.

(d) Shipments of a medical device in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the medical device's intended uses. A manufacturer cannot market its device for a new intended use without notifying the FDA via a new 510(k) premarket notification. The failure to notify the FDA of a new intended use misbrands the device.

(e) In December 2001, Norian SRS, a calcium phosphate compound, was cleared via the 510(k) process by the FDA as a bone void filler, to fill only those bony voids that were not intrinsic to the stability of the bony structure, in the extremities, spine and pelvis. The Norian SRS label stated further that SRS was not to be mixed with any other substance. In December 2002, the successor device, Norian

XR, which consisted of calcium phosphate with barium sulfate added for extra radiopacity, was cleared via the Special 510(k) process by the FDA, also as a bone void filler, with an indication statement identical to that of SRS. The Norian XR label further contained a warning: "not intended for treatment of vertebral compression fractures."

(f) Earlier, but no later than May 2002, Synthes and Norian learned that the FDA was concerned over the imprecision of the spine indication in the then-current indication for use of bone void fillers, and that the FDA understood that some surgeons, as part of their practice of medicine, were using bone void fillers in the spine for load bearing indications. The FDA asked that Synthes and Norian -- in their pre-market notification to the FDA seeking clearance of Norian XR -- provide additional labeling for Norian XR that specified that spinal load-bearing indications, such as vertebroplasty, were not included in the product's indication for use. Synthes and Norian then promised the FDA that the companies would not promote Norian XR for vertebroplasty or other spinal load-bearing indications without the appropriate regulatory authority. The FDA continued to request such labeling until Synthes submitted the warning against vertebral compression fracture ("VCF") use that became a part of the Norian XR label.

(g) Between August 2002 and December 2002, Synthes and Norian trained spine surgeons to mix Norian SRS with barium sulfate and to use the resulting medical device in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian SRS stated that the product was not to be mixed with any other

substance. This training of surgeons to mix Norian SRS with barium sulfate for the treatment of VCFs violated 21 U.S.C. §§ 351(f)(1)(B), 352(o) and 352(f)(1) because the mixing made SRS a new device that required premarket approval or clearance for this new intended use, and that lacked adequate directions for such use.

(h) Between August 2003 and January 2004, Synthes and Norian trained spine surgeons to use Norian XR in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. This training took place as part of an illegal so-called "test market" for Norian XR. As part of the XR "test market," Synthes and Norian directed the Synthes Spine sales force to gather clinical data about surgeries that the "test market" surgeons performed, so that Synthes and Norian could document the results of surgeries to treat VCFs, in order to assess the risk level of using Norian XR to treat VCFs, and determine whether that risk level was too high. This unauthorized clinical testing of Norian XR for the treatment of VCFs violated 21 U.S.C. § 351(f)(1) because such testing of a significant risk device required the prior approval of the FDA, through an IDE.

(I) Between December 2002 and January 2004, Synthes and Norian promoted Norian XR for use in vertebroplasty-type surgeries to treat VCFs, nothwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. The promotion of Norian XR for this additional intended use violated 21 U.S.C. § 351(f)(1), because Norian XR's labeling did not bear adequate directions

for each of the device's intended uses, and in fact, warned against the intended use of treating VCFs.

(j) In May and June 2004, Synthes and Norian were the subject of an unannounced inspection by the FDA. During the inspection, employees of Synthes and Norian knowingly made material false statements to the FDA investigator, concerning the training of spine surgeons to mix Norian SRS with barium sulfate for the treatment of VCFs, and the illegal so-called "test market" for Norian XR.

8. Except as provided herein, the United States agrees that, other than the charges in the Superseding Information in this case, it will not bring any other criminal charges against Norian, its present and former parents, affiliates, divisions, and subsidiaries, and its present and former officers, directors, employees and agents; their predecessors, successors and assigns for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to Norian's medical devices Norian CRS, Norian SRS and Norian XR; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Norian CRS, Norian SRS or Norian XR in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice. Attached as Exhibit B is a copy of the letter to United States Attorney

Michael L. Levy from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

9. Norian understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice except as specified in paragraph 8 of this guilty plea agreement. Further, Norian understands that the United States takes no position as to the proper tax treatment of any of the payments made by Norian pursuant to this plea agreement.

10. The defendant understands and agrees that in the event that this agreement is not consummated, any party withdraws from it, or it is otherwise not fully carried out, including the circumstances described in paragraph 3(a) through (h) above, defendant Norian may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of its investigation, notwithstanding the expiration of any applicable statute of limitations between the time when Norian signed this plea agreement and the occurrence of any of the above events. In that event, Norian (1) waives all defenses based on speedy trial under the Constitution or Speedy Trial Act, and any statutes of limitations, for 90 days from the latest of these events; and (2) agrees that Norian will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of a Tolling Agreement between the parties effective August 17, 2007, all subsequent extensions of the Tolling Agreement, and this paragraph.

11. In exchange for the undertakings made by the government in entering this plea agreement, Norian voluntarily and expressly waives all rights to appeal or collaterally attack

the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

12. Norian also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

13. Norian is satisfied with the legal representation provided by its lawyers; Norian and its lawyers have fully discussed this guilty plea agreement; and Norian is agreeing to plead guilty because Norian admits that it is guilty of the felony and misdemeanor offenses described in paragraph 1.

14. Norian will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. Norian shall provide to the government for attachment as Exhibit C to this plea agreement a notarized resolution by Norian's board of directors authorizing the corporation to enter pleas of guilty, and authorizing a corporate officer to execute this agreement.

15. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Norian be sentenced at the time the guilty plea is entered.

16. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement. No additional promises, agreements or understandings will be entered into unless in

unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

ANN M. RAVEL
Acting Assistant Attorney General
Civil Division
United States Department of Justice

EUGENE M. THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

JOEL D. SCHWARTZ
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

MICHAEL L. LEVY
United States Attorney
Eastern District of Pennsylvania

PETER F. SCHENCK
Chief, Criminal Division
Assistant United States Attorney

JOHN J. PEASE
Assistant United States Attorney
Chief, Health Care Fraud Section

MARY E. CRAWLEY
Assistant United States Attorney

GERALD B. SULLIVAN
Assistant United States Attorney

DAVID J. CAPUTO
Assistant United States Attorney

DATE: _____

writing and signed by all parties.

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Chief, Health Care Fraud Section

MARY E. CRAWLEY
Assistant United States Attorney

GERALD B. SULLIVAN
Assistant United States Attorney

DAVID J. CAPUTO
Assistant United States Attorney

DATE: _____

SIGNATURE FOR NORIAN

DATE: October 16, 2009

MICHEL ORSINGER
President
Norian Corporation

SIGNATURE OF NORIAN'S ATTORNEY

DATE: _____

JAMES T. SMITH
Blank Rome LLP
Counsel for Defendant

SIGNATURE FOR NORIAN

DATE: _____

_____
MICHEL ORSINGER
President
Norian Corporation

SIGNATURE OF NORIAN'S ATTORNEY

DATE: 10-16-09

_____
JAMES T. SMITH
Blank Rome LLP
Counsel for Defendant

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	CRIMINAL NO. 09-403-1
NORIAN CORPORATION	:	

ACKNOWLEDGMENT OF RIGHTS

Norian Corporation ("Norian"), through its properly authorized officer, hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. Norian understands that it does not have to plead guilty.

2. Norian may plead not guilty and insist upon a trial.

3. At that trial, Norian understands:

   a. that Norian would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, Norian would have the right to participate in the selection of that jury;

   b. that the jury could only convict Norian if all twelve jurors agreed that they were convinced of Norian's guilt beyond a reasonable doubt;

   c. that the government would have the burden of proving Norian's guilt beyond a reasonable doubt and that Norian would not have to prove anything;

   d. that Norian would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that Norian was guilty;

   e. that Norian would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if Norian could not afford to hire a lawyer, the court would appoint one for Norian free of charge;

   f. that through Norian's lawyer Norian would have the right to confront and cross-examine the witnesses against Norian;

g. that Norian could call witnesses to testify in its defense if Norian wanted to, and Norian could subpoena witnesses for this purpose if Norian wanted to; and

h. that Norian would not have to call witnesses to testify or otherwise present any defense if Norian did not want to, and that if Norian did not present any evidence, the jury could not hold that against Norian.

4. Norian understands that if Norian pleads guilty, there will be no trial and Norian would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.

5. Norian understands that if Norian decides to enter a plea of guilty, the judge will ask Norian representatives questions under oath, and that if any of those representatives lie on behalf of Norian in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.

6. Norian understands that if Norian pleads guilty, Norian has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.

7. Understanding that Norian has all these rights and that by pleading guilty Norian is giving them up, Norian still wishes to plead guilty.

M. Orsinger 10/16/09

MICHEL ORSINGER
President
Norian Corporation

JAMES T. SMITH
Blank Rome LLP
Counsel for Defendant

g. that Norian could call witnesses to testify in its defense if Norian wanted to, and Norian could subpoena witnesses for this purpose if Norian wanted to; and

h. that Norian would not have to call witnesses to testify or otherwise present any defense if Norian did not want to, and that if Norian did not present any evidence, the jury could not hold that against Norian.

4. Norian understands that if Norian pleads guilty, there will be no trial and Norian would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.

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6. Norian understands that if Norian pleads guilty, Norian has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.

7. Understanding that Norian has all these rights and that by pleading guilty Norian is giving them up, Norian still wishes to plead guilty.

MICHEL ORSINGER
President
Norian Corporation

JAMES T. SMITH
Blank Rome LLP
Counsel for Defendant

EXHIBIT B

IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	**CRIMINAL NO. 09 - 403 - 02**
SYNTHES, INC.	:	

GUILTY PLEA AGREEMENT

Under Federal Rule of Criminal Procedure 11(c)(1)(C), the government, the defendant, Synthes, Inc. (hereinafter "Synthes"), and Synthes's counsel enter into the following guilty plea agreement. Any reference to the United States or the government in this agreement shall mean the Office of the United States Attorney for the Eastern District of Pennsylvania and the Office of Consumer Litigation of the United States Department of Justice.

1. Synthes agrees to plead guilty to Count Two of a Superseding Information, waiving prosecution by indictment, charging it with one count of the introduction into interstate commerce of medical devices that were adulterated pursuant to 21 U.S.C. § 351(f)(1)(B), and misbranded pursuant to 21 U.S.C. §§ 352(f), (o), a misdemeanor, in violation of 21 U.S.C. §§ 331(a) and 333(a)(1). Synthes further acknowledges its waiver of rights, as set forth in Exhibit A to this agreement.

2. This agreement is conditioned upon the following: (a) Synthes's subsidiary, Norian Corporation ("Norian") entering a guilty plea in this case; and (b) acceptance of that plea by the United States District Court at the time of the guilty plea hearing. If conditions 2(a) and 2(b) are not satisfied, or if Norian subsequently seeks to withdraw its guilty plea, the United States, in its sole discretion, will be released from all of its obligations under this

agreement. In addition, if defendant Norian breaches its plea agreement, the United States, in its sole discretion, may void this defendant's plea agreement.

3. With regard to the Superseding Information to be filed pursuant to this agreement, defendant Synthes waives all defenses based on speedy trial under the Constitution or Speedy Trial Act, and any statutes of limitations. The defendant agrees that prosecution of the offense described in paragraph one above is timely as of the date that this agreement is signed and as of the date that the guilty plea will be entered in District Court. In the event that this agreement is not consummated, any party withdraws from it, or it is otherwise not fully carried out, including the following circumstances described in subparagraphs (a) through (h) of this paragraph, the defendant waives all defenses based on speedy trial and any statute of limitations with respect to the charge set forth in the Superseding Information to be filed pursuant to this agreement, for 90 days from the latest of any of these events: (a) Synthes's guilty plea is not accepted by the Court for any reason; (b) Norian's guilty plea is not accepted by the Court for any reason; (c) Synthes's conviction is later vacated for any reason; (d) Norian's conviction is later vacated for any reason; (e) Synthes violates this agreement; (f) Norian violates its plea agreement; (g) Synthes's plea is later withdrawn; or (h) Norian's plea is later withdrawn.

4. The parties agree that this plea agreement is made pursuant to Fed.R.Crim.P. 11(c)(1)(C) and that the following specific sentence is the appropriate disposition of this case. Taking into consideration the factors set forth in 18 U.S.C. §§ 3553(a) and 3572, the agreed upon sentence is as follows:

A. Synthes agrees to pay the special assessment in the amount of $125 on the date of sentencing.

B. Synthes agrees to pay $669,800 to resolve the Superseding Information, of which $200,000 will be applied as a criminal fine, and $469,800 will be applied as substitute assets to satisfy the forfeiture obligation described in paragraph 4(C) below. Synthes will pay these amounts within 3 business days after the date of sentencing. Synthes and the government agree that this fine and forfeiture represent a fair and just resolution of all issues associated with loss, fine and forfeiture calculations. Synthes and the government agree that no order of restitution is appropriate in light of the anticipated, separate civil settlement agreement involving the same conduct described in the Superseding Information, and to avoid unduly complicating and prolonging the sentencing process.

C. Synthes agrees that as a result of its acts or omissions, the forfeitable property, that is the medical devices that were illegally test marketed and promoted, are no longer available for forfeiture because the devices cannot be located or have been transferred, sold or deposited with a third party, or otherwise disposed of, within the meaning of federal law. As a result, Synthes agrees to the entry and satisfaction of a judgment and preliminary order of forfeiture on the date of the guilty plea, forfeiting to the United States the sum of $469,800 as substitute assets for the pertinent devices. Synthes agrees that, within 3 business days after the date of sentencing, Synthes will make payment to the United States, by means of a wire transfer to the United States Marshals Service or check payable to same, in the amount of $469,800, this amount representing substitute assets of the offense for which it is pleading guilty, subject to forfeiture in full satisfaction of the judgment and preliminary order of forfeiture.

D. In light of an anticipated Corporate Integrity Agreement between Synthes and the Office of Inspector General of the United States Department of Health and Human Services, Synthes will not be placed on probation.

5. Synthes's subsidiary Norian intends to execute a guilty plea agreement to one count of conspiracy to impair and impede the lawful functioning of the Food and Drug Administration ("FDA") and to commit offenses against the United States, in violation of 18 U.S.C. § 371, and 110 counts of introducing into interstate commerce medical devices that were adulterated pursuant to 21 U.S.C. § 351(f)(1)(B), and misbranded pursuant to 21 U.S.C. §§ 352(f), (o), which are misdemeanor violations of 21 U.S.C. §§ 331(a) and 333(a)(1). As stated above in paragraph 2, Synthes's guilty plea is conditioned upon the guilty plea of Norian. In addition, Synthes waives any and all defenses and objections in this matter or in that proceeding that might be available under the Double Jeopardy and Excessive Fines clauses of the Eighth Amendment.

6. Synthes waives any claim under the Hyde Amendment, 18 U.S.C. § 3006A (Statutory Note), for attorney's fees and other litigation expenses arising out of the investigation or prosecution of this matter.

7. Synthes understands, agrees and has had explained to it by counsel that the Court may impose the following statutory maximum sentence: a fine of $200,000, or twice the gross gain or gross loss, whichever is greater; $469,800 in criminal forfeiture; a special assessment of $125; restitution if ordered by the Court; and a five-year term of Court supervision. Synthes further understands that the terms and conditions of any Court supervision may be

changed, and extended, by the Court if Synthes violates any of the terms and conditions of that supervision.

8. With respect to Synthes's conduct, the parties stipulate to the following facts and basis for the plea and criminal fine:

(a) Synthes and its subsidiary, Norian, marketed Norian CRS, Norian SRS and Norian XR, each of which was a medical device within the meaning of 21 U.S.C. § 321(h)(1), and a significant risk device within the meaning of 21 C.F.R. § 812(m)(1).

(b) Significant risk devices cannot be clinically tested without prior approval of the FDA, which approval is given through an investigational device exemption (IDE).

(c) In the context of medical devices, clinical testing means research on one or more human subjects to determine the safety or effectiveness of the device.

(d) Shipments of a medical device in interstate commerce must be accompanied by labeling bearing adequate directions for use for each of the medical device's intended uses. A manufacturer cannot market its device for a new intended use without notifying the FDA via a new 510(k) premarket notification. The failure to notify the FDA of a new intended use misbrands the device.

(e) In December 2001, Norian SRS, a calcium phosphate compound, was cleared via the 510(k) process by the FDA as a bone void filler, to fill only those bony voids that were not intrinsic to the stability of the bony structure, in the extremities, spine and pelvis. The Norian SRS label stated further that SRS was not to be mixed with any other substance. In December 2002, the successor device, Norian

XR, which consisted of calcium phosphate with barium sulfate added for extra radiopacity, was cleared via the Special 510(k) process by the FDA, also as a bone void filler, with an indication statement identical to that of SRS. The Norian XR label further contained a warning: "not intended for treatment of vertebral compression fractures."

(f) Earlier, but no later than May 2002, Synthes and Norian learned that the FDA was concerned over the imprecision of the spine indication in the then-current indication for use of bone void fillers, and that the FDA understood that some surgeons, as part of their practice of medicine, were using bone void fillers in the spine for load-bearing indications. The FDA asked that Synthes and Norian – in their pre-market notification to the FDA seeking clearance of Norian XR -- provide additional labeling for Norian XR that specified that spinal load-bearing indications, such as vertebroplasty, were not included in the product's indication for use. Defendants Synthes and Norian then promised the FDA that the companies would not promote Norian XR for vertebroplasty or other spinal load-bearing indications without the appropriate regulatory authority. The FDA continued to request such labeling until Synthes submitted the warning against vertebral compression fracture ("VCF") use that became a part of the Norian XR label.

(g) Between August 2002 and December 2002, Synthes and Norian trained spine surgeons to mix Norian SRS with barium sulfate and to use the resulting medical device in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the

label of Norian SRS stated that the product was not to be mixed with any other substance. This training of surgeons to mix Norian SRS with barium sulfate for the treatment of VCFs violated 21 U.S.C. §§ 351(f)(1)(B), 352(o) and 352(f)(1) because the mixing made SRS a new device that required premarket approval or clearance for this new intended use, and that lacked adequate directions for such use.

(h) Between August 2003 and January 2004, Synthes and Norian trained spine surgeons to use Norian XR in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. This training took place as part of an illegal so-called "test market" for Norian XR. As part of the XR "test market," Synthes and Norian directed the Synthes Spine sales force to gather clinical data about surgeries that the "test market" surgeons performed, so that Synthes and Norian could document the results of surgeries to treat VCFs, in order to assess the risk level of using Norian XR to treat VCFs, and determine whether that risk level was too high. This unauthorized clinical testing of Norian XR for the treatment of VCFs violated 21 U.S.C. § 351(f)(1) because such testing of a significant risk device required the prior approval of the FDA, through an IDE.

(I) Between December 2002 and January 2004, Synthes and Norian promoted Norian XR for use in vertebroplasty-type surgeries to treat VCFs, notwithstanding that the label of Norian XR warned that the product was not intended for treatment of VCFs. The promotion of Norian XR for this additional intended use violated 21

U.S.C. § 351(f)(1), because Norian XR's labeling did not bear adequate directions for each of the device's intended uses, and in fact, warned against the intended use of treating VCFs.

9. Except as provided herein, the United States agrees that, other than the charges in the Superseding Information in this case, it will not bring any other criminal charges against Synthes, its present and former parents, affiliates, divisions, and subsidiaries, and its present and former officers, directors, employees and agents; their predecessors, successors and assigns for conduct which (A) falls within the scope of the criminal investigation in the Eastern District of Pennsylvania relating to Synthes's medical devices Norian CRS, Norian SRS and Norian XR; or (B) was known to the United States Attorney's Office for the Eastern District of Pennsylvania or the Office of Consumer Litigation of the Department of Justice as of the date of the execution of this plea agreement, and which concerned the sale, promotion, or marketing of Norian CRS, Norian SRS or Norian XR in the United States. The non-prosecution provisions of this paragraph are binding on the Office of the United States Attorney for the Eastern District of Pennsylvania, the Office of Consumer Litigation of the Department of Justice, and the United States Attorney's Offices for each of the other 93 judicial districts of the United States. The non-prosecution provisions are also binding on the Criminal Division of the United States Department of Justice. Attached as Exhibit B is a copy of the letter to United States Attorney Michael L. Levy from the Assistant Attorney General, Criminal Division, Department of Justice, authorizing this agreement.

10. Synthes understands that this guilty plea agreement does not bind any other government agency, or any component of the Department of Justice, except as specified in

paragraph 9 of this guilty plea agreement. Further, Synthes understands that the United States takes no position as to the proper tax treatment of any of the payments made by Synthes pursuant to this plea agreement.

11. The defendant understands and agrees that in the event that this agreement is not consummated, any party withdraws from it, or it is otherwise not fully carried out, including the circumstances described in paragraph 3(a) through (h) above, defendant Synthes may thereafter be prosecuted for any criminal violation of which the United States has knowledge arising out of its investigation, notwithstanding the expiration of any applicable statute of limitations between the time when Synthes signed this plea agreement and the occurrence of any of the above events. In that event, Synthes (1) waives all defenses based on speedy trial under the Constitution or Speedy Trial Act, and any statutes of limitations, for 90 days from the latest of these events; and (2) agrees that Synthes will not raise the expiration of any statute of limitations as a defense to any such prosecution, except to the extent that the statute of limitations would have been a defense pursuant to the terms of a Tolling Agreement between the parties effective August 17, 2007, all subsequent extensions of the Tolling Agreement, and this paragraph.

12. In exchange for the undertakings made by the government in entering this plea agreement, Synthes voluntarily and expressly waives all rights to appeal or collaterally attack the defendant's conviction, sentence, or any other matter relating to this prosecution, whether such a right to appeal or collateral attack arises under 18 U.S.C. § 3742, 28 U.S.C. § 1291, 28 U.S.C. § 2255, or any other provision of law. This waiver is not intended to bar the assertion of constitutional claims that the relevant case law holds cannot be waived.

13. Synthes also waives all rights, whether asserted directly or by a representative, to request or receive from any department or agency of the United States any records pertaining to the investigation or prosecution of this case, including without limitation any records that may be sought under the Freedom of Information Act, 5 U.S.C. § 552, or the Privacy Act, 5 U.S.C. § 552a.

14. Synthes is satisfied with the legal representation provided by its lawyers; Synthes and its lawyers have fully discussed this guilty plea agreement; and Synthes is agreeing to plead guilty because Synthes admits that it is guilty of the misdemeanor offense described in paragraph 1.

15. Synthes will acknowledge acceptance of this guilty plea agreement by the signature of its counsel and of an authorized corporate officer. Synthes shall provide to the government for attachment as Exhibit C to this plea agreement a notarized resolution by Synthes's board of directors authorizing the corporation to enter a plea of guilty, and authorizing a corporate officer to execute this agreement.

16. If acceptable to the Court, the parties agree to waive the presentence investigation and report pursuant to Rule 32(c)(1) of the Federal Rules of Criminal Procedure, and ask that Synthes be sentenced at the time the guilty plea is entered.

17. It is agreed that the parties' guilty plea agreement contains no additional promises, agreements or understandings other than those set forth in this written guilty plea agreement, and that no additional promises, agreements or understandings will be entered into

unless in writing and signed by all parties.

SIGNATURES FOR THE UNITED STATES

ANN M. RAVEL
Acting Assistant Attorney General
Civil Division
United States Department of Justice

EUGENE M. THIROLF
Director, Office of Consumer Litigation
United States Department of Justice

JOEL D. SCHWARTZ
Trial Attorney
Office of Consumer Litigation
United States Department of Justice

MICHAEL L. LEVY
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Eastern District of Pennsylvania

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Assistant United States Attorney
Chief, Health Care Fraud Section

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GERALD B. SULLIVAN
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Assistant United States Attorney

DATE: _____

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Chief, Health Care Fraud Section

MARY E. CRAWLEY
Assistant United States Attorney

GERALD B. SULLIVAN
Assistant United States Attorney

DAVID J. CAPUTO
Assistant United States Attorney

DATE: _____

SIGNATURE FOR SYNTHES

DATE: October 16, 2009

MICHEL ORSINGER
President and Chief Executive Officer
Synthes, Inc.

SIGNATURE OF SYNTHES'S ATTORNEY

DATE: _____

DONALD J. GOLDBERG
Ballard Spahr Andrews and Ingersoll
Counsel for Defendant

SIGNATURE FOR SYNTHES

DATE: _____

_____
MICHEL ORSINGER
President and Chief Executive Officer
Synthes, Inc.

SIGNATURE OF SYNTHES'S ATTORNEY

DATE: 10-16-09

_____
DONALD J. GOLDBERG
Ballard Spahr Andrews and Ingersoll
Counsel for Defendant

Exhibit A

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	
v.	:	CRIMINAL NO. 09-403-02
SYNTHES, INC.	:	

ACKNOWLEDGMENT OF RIGHTS

Synthes, Inc. ("Synthes"), through its properly authorized officer, hereby acknowledges that it has certain rights that it will be giving up by pleading guilty.

1. Synthes understands that it does not have to plead guilty.

2. Synthes may plead not guilty and insist upon a trial.

3. At that trial, Synthes understands:

   a. that Synthes would have the right to be tried by a jury that would be selected from the Eastern District of Pennsylvania and that along with its attorney, Synthes would have the right to participate in the selection of that jury;

   b. that the jury could only convict Synthes if all twelve jurors agreed that they were convinced of Synthes's guilt beyond a reasonable doubt;

   c. that the government would have the burden of proving Synthes's guilt beyond a reasonable doubt and that Synthes would not have to prove anything;

   d. that Synthes would be presumed innocent unless and until such time as the jury was convinced beyond a reasonable doubt that the government had proven that Synthes was guilty;

   e. that Synthes would have the right to be represented by a lawyer at this trial and at any appeal following the trial, and that if Synthes could not afford to hire a lawyer, the court would appoint one for Synthes free of charge;

f. that through Synthes's lawyer Synthes would have the right to confront and cross-examine the witnesses against Synthes;

g. that Synthes could call witnesses to testify in its defense if Synthes wanted to, and Synthes could subpoena witnesses for this purpose if Synthes wanted to; and

h. that Synthes would not have to call witnesses to testify or otherwise present any defense if Synthes did not want to, and that if Synthes did not present any evidence, the jury could not hold that against Synthes.

4. Synthes understands that if Synthes pleaded guilty, there will be no trial and Synthes would be giving up all of the rights listed above, as well as any other rights associated with the trial process arising under statute, common-law, or judicial precedent.

5. Synthes understands that if Synthes decides to enter a plea of guilty, the judge will ask Synthes representatives questions under oath, and that if any of those representatives lie on behalf of Synthes in answering those questions, those persons could be prosecuted for the crime of perjury, that is, for lying under oath.

6. Synthes understands that if Synthes pleads guilty, Synthes has waived its right to appeal, except as set forth in appellate waiver provisions of the plea agreement.

7. Understanding that Synthes has all these rights and that by pleading guilty Synthes is giving them up, Synthes still wishes to plead guilty.

MICHEL ORSINGER
President and Chief Executive Officer
Synthes, Inc.

10/16/09

DONALD J. GOLDBERG
Ballard Spahr Andrews and Ingersoll
Counsel for Defendant

f. that through Synthes's lawyer Synthes would have the right to confront and cross-examine the witnesses against Synthes;

g. that Synthes could call witnesses to testify in its defense if Synthes wanted to, and Synthes could subpoena witnesses for this purpose if Synthes wanted to; and

h. that Synthes would not have to call witnesses to testify or otherwise present any defense if Synthes did not want to, and that if Synthes did not present any evidence, the jury could not hold that against Synthes.

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